

Notice of Allowability

Application No.

10/693,375

Examiner

Deborah Malamud

Applicant(s)

CHO ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 15 June 2006.
2. ☒ The allowed claim(s) is/are 14-15, 17, 19-22, 24-48, 50, 52-77, 79 and 81-93.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 7/27/06.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

1. The examiner acknowledges the amendments received 15 June 2006. Claims 1-13, 16, 18, 49, 51, 78 and 80 are cancelled. Claims 14-15, 17, 19-48, 50, 52-77, 79 and 81-93 are pending.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. Authorization for this examiner's amendment was given in a telephone interview with Daniel Chapik on 27 July 2006.

The application has been amended as follows:

In the claims:

Claim 23 is cancelled

Claim 14, line 7 of the claim, immediately after "...therapy;...", --means for determining a cycle length of a sleep-disordered breathing episode, wherein the means for delivering augmentation therapy deliver the therapy for a period of time based on the determined cycle length-- was inserted.

Claim 14, line 10 of the claim, immediately after "...determined based...", --on-- was inserted.

Drawings

4. The replacement drawing sheets were received on 15 June 2006. These drawings are acceptable.

Claim Objections

5. In view of the amendments to the claims, the examiner withdraws the objection to claim 76.

Claim Rejections - 35 USC § 112

6. In view of the amendments to the claims, the examiner withdraws the rejections of claims 48, 50 and 79 under 35 USC 112, second paragraph.

Claim Rejections - 35 USC § 102

7. In view of the cancellation of claims 1-13, the examiner's amendment and the amendments made by the applicant to the claims, the examiner withdraws the rejection under 35 USC 102(e) of claims 1-7, 11-12, 14-17, 23-24, 34-36, 45-50, 52, 62-65, 74-76, 78-79, 81 and 91-93.

Claim Rejections - 35 USC § 103

8. In view of the cancellation of claims 1-13, the examiner's amendment and the amendments made by the applicant to the claims, the examiner withdraws the rejection under 35 USC 103(a) of claims 8-11, 13, 16, 26-33, 37-44 and 66-73.

Allowable Subject Matter

9. Claims 14-15, 17, 19-22, 24-48, 50, 52-77, 79 and 81-93 are allowed.

10. The following is an examiner's statement of reasons for allowance:

Claim 14, as amended, is an implantable medical device (IMD) for delivery therapy for sleep-disordered breathing (SDB) comprising means for determining the presence of sleep-disordered breathing; means for delivering augmentation therapy when the means for determining indicates the presence of SDB; means for providing atrial pacing in combination with the augmentation therapy; means for determining a cycle length of a SDB episode, wherein the means for delivering augmentation therapy deliver the therapy for a period of time based on the determined cycle length; and means for calculating a mean heart rate, wherein the means for providing atrial pacing pace the atria at an atrial rate that is a multiple of a desired ventricular rate and the desired ventricular rate is determined based on the mean heart rate.

Implantable devices that determine the presence of apnea or other SBD are common in the art, as are devices that deliver electrical stimulation to the heart once SDB are indicated as occurring. Usually the electrical stimulation is excitatory, and is delivered in the form of cardiac pacing. The specific means for determining a cycle

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length of a sleep-disordered breathing episode and then delivering therapy for the determined cycle length of the SDB are neither stated explicitly in the references nor obvious to one of ordinary skill in the art at the time the invention was made.

Claim 36, as amended, is a method of utilizing an IMD to provide therapy for SDB comprising determining if SDB is present; delivering augmentation therapy in the form of electrical stimulation to cardiac tissue if SDB is determined to be present; determining a cycle length for a SDB episode; and delivering the augmentation therapy for X number of cardiac cycles, wherein X is selected based on the determined cycle length, wherein the cycle length is an averaged value of multiple SDB breathing episodes. Claim 65, as amended is a computer readable medium containing instructions that when implemented, cause an IMD to perform actions to provide therapy for SDB, the actions comprising determining if SDB is present; delivering augmentation therapy in the form of electrical stimulation to cardiac tissue if SDB is determined to be present; determining a cycle length for a SDB episode; and delivering the augmentation therapy for X number of cardiac cycles, wherein X is selected based on the determined cycle length, wherein the cycle length is an averaged value of multiple SDB breathing episodes.

Determining if SDB is present and delivering electrical stimulation to the heart if SDB is present is common in the art. The step of determining a cycle length for a SDB episode and delivering the therapy for a number of cycles selected based on the averaged cycle length of multiple sleep-disordered breathing episodes is neither taught

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nor suggested in the art, nor would it have been obvious to one of ordinary skill in the art at the time of the invention.

11. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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